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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,737	09/29/2003	Lisa Donnelly	22956-0743(MIT5021)	1928

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EXAMINER
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COMSTOCK, DAVID C

ART UNIT	PAPER NUMBER
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3733

NOTIFICATION DATE	DELIVERY MODE
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02/19/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/673,737	<b>Applicant(s)</b> DONNELLY ET AL.	
	<b>Examiner</b> DAVID COMSTOCK	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beck, Jr. et al. (5,632,748) in view of Wenstrom, Jr. et al. (6,325,804; cited by Applicant); or in the alternative, in view of Agrawal (WO 96/00592; cited by Applicant).

Beck, Jr. et al. disclose providing a graft 16 in bone tunnels 10 formed in the femur 10 and tibia. See, e.g., Fig. 1 and col. 6, line 24 - col. 7, line 24 and col. 15, lines 45-51. The grafts are secured in the tunnels by an interference screw 28 that may be formed of biodegradable materials (id.). The tunnels are tapped by the self-tapping threads of the device. See, e.g., Fig. 1 and col. 7, lines 35-62. Beck, Jr. et al. do not explicitly recite the biodegradable material comprising a copolymer of polylactic or polyglycolic acid and a bioceramic such as TCP or other calcium phosphates, hydroxyapatite, calcium sulfates, calcium oxides, calcium carbonates, and magnesium phosphates.

Wenstrom, Jr. et al. teach that biodegradable implant materials may comprise a copolymer of polylactic acid, polyglycolic acid, and a bioceramic (see, e.g., col. 6, lines 44-50). Wenstrom, Jr. et al. teach that these materials and a copolymer of them are

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known suitable materials for use in a biodegradable implant. It would have been obvious to have performed the method of Beck, Jr. et al. using an interference screw formed of a copolymer of polylactic acid, polyglycolic acid, and a bioceramic, such as tri-calcium phosphate or other calcium phosphates, hydroxyapatite, calcium sulfates, calcium oxides, calcium carbonates, and magnesium phosphates, in view of Wenstrom, Jr. et al., e.g., to provide a material that is suitable for a biodegradable implant, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. It also would have been obvious to provide the copolymer of polylactic or polyglycolic acid in an amount comprising about 85 mole percent to about 95 mole percent of polylactic acid and about 5 mole percent to about 15 mole percent of polyglycolic acid; and to provide the bioceramic in an amount of about 2.0 volume percent to about 25.0 volume percent of bioceramic, or about 15.0 volume percent, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. It is noted that Wenstrom, Jr., et al. disclose that "any copolymers, mixtures or blends" of the above-noted materials may be used, and the above amounts necessarily fall within the scope of this disclosure.

Agrawal teaches that biodegradable implants may be formed of copolymers of polylactic acid and polyglycolic acid and a bioceramic (see, e.g., page 8, lines 12-22, page 9, lines 29-34, page 9, lines 32 and 33, page 10, lines 19-22, page 16, lines 3-26, etc.). Agrawal teaches that the disclosed materials are biodegradable and also have

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sufficient elastic modulus to be useful for bearing loads (see, e.g., page 4, lines 23-26).

Therefore, it also would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Beck, Jr. et al. using a biodegradable interference screw formed of a copolymer of polylactic acid and polyglycolic acid and a bioceramic, in view of Agrawal, in order to provide a screw that is both biodegradable but also that has sufficient elastic modulus to not break. It is noted that while a plate is exemplified by Agrawal, the teachings regarding the improved biodegradable material would also be relevant to other biodegradable structural implants such as screws, which are mentioned along with plates in the background (where the shortcomings of the prior art were discussed, implying that these structures could benefit from the material of the invention set forth in the reference). See, e.g., page, 3, lines 6 and 7 and page 4, lines 1-3. It also would have been obvious to provide the copolymer of polylactic or polyglycolic acid in an amount comprising about 85 mole percent to about 95 mole percent of polylactic acid and about 5 mole percent to about 15 mole percent of polyglycolic acid; and to provide the bioceramic in an amount of about 2.0 volume percent to about 25.0 volume percent of bioceramic, or about 15.0 volume percent, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. It is noted that the detailed disclosure of various specific amounts of the relevant materials throughout the disclosure, examples, and claims, and their resulting properties, demonstrates that the materials provided in varying amounts were recognized as result-effective variables.

***Response to Arguments***

Applicant's arguments filed 25 August 2009 have been fully considered but they are not persuasive.

Examiner maintains each of the outstanding grounds of rejection and every point set forth in the Interview Summary mailed 02 July 2009. Beck, Jr. et al. was cited for a bone screw implant, while Wenstrom, Jr. et al. and Agrawal are cited for their teaching regarding the suitability and advantage of using the claimed material for an implant. Applicant's assertion that Examiner has not provided a reason for making the modification set forth in the rejection is clearly inaccurate as can be seen by reviewing the grounds of rejection above. The rejection is not based on hindsight. With regard to Wenstrom, Jr. et al., it would have been obvious to have performed the method of Beck, Jr. et al. using an interference screw formed of a copolymer of polylactic acid, polyglycolic acid, and a bioceramic, such as tri-calcium phosphate or other calcium phosphates, hydroxyapatite, calcium sulfates, calcium oxides, calcium carbonates, and magnesium phosphates, in view of Wenstrom, Jr. et al., to provide a material that is suitable for a biodegradable implant, as taught by Wenstrom, Jr. et al. (see, e.g., col. 6, lines 44-50).

Agrawal teaches that biodegradable implants may be formed of copolymers of polylactic acid and polyglycolic acid and a bioceramic (see, e.g., page 8, lines 12-22, page 9, lines 29-34, page 9, lines 32 and 33, page 10, lines 19-22, page 16, lines 3-26, etc.). Agrawal teaches that the disclosed materials are biodegradable and also have sufficient elastic modulus to be useful for bearing loads (see, e.g., page 4, lines 23-26).

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Therefore, as set forth in the rejection, it also would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Beck, Jr. et al. using a biodegradable interference screw formed of a copolymer of polylactic acid and polyglycolic acid and a bioceramic, in view of Agrawal, in order to provide a screw that is both biodegradable but also that has sufficient elastic modulus to not break.

The intended use of providing a bioresorbable implant in a bone tunnel is satisfied by the prior art. It is noted that Wenstrom et al. set forth resorbable devices for implantation in a bone tunnel that are subject to shear forces. Applicant's argument that using the claimed materials produces unexpected results is not persuasive because the prior art discloses the use of the claimed material for an implant and for an implant in a bone tunnel and subject to shearing forces. Moreover, as set forth in the rejection, the combination of materials was known to counteract the otherwise brittle nature of bioceramics. Therefore it cannot be unexpected if the prior art already combines the claimed materials and notes that this is suitable for implants and allows the implant to be both biodegradable and to still have a sufficient elastic modulus to not break. Accordingly, the rejection is maintained.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710 (a detailed message should be left if Examiner is unavailable). If attempts to

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reach the Examiner by telephone or voicemail are unsuccessful, the examiner's supervisor, Eduardo Robert, can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David Comstock/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733